

### **REMARKS**

Please reconsider the application in view of the above amendments and the following remarks. No new matter has been added by way of the amendments. Applicant thanks the Examiner for the courtesies extended during the Examiner Interview of February 20, 2007, and the supplemental teleconference of February 22, 2007, and for indicating that claims 6, and 19-24 are allowed.

#### **Preliminary Matters**

Claim 1 is included in the list of pending claims in the Office Action Summary. Claim 1 was cancelled in Applicant's reply to the Office Action of August 1, 2006. Accordingly, Applicant respectfully requests clarification of the status of claim 1.

#### **Disposition of Claims**

Claims 2-7, 9-14, 16-17, and 19-26 were pending in this application. Claims 5, 9, 16, 17, and 25 have been cancelled by this reply. Claims 6, 20, and 26, are independent. The remaining claims depend, directly or indirectly, from independent claims 6, 20, and 26.

#### **Examiner Interview**

An Examiner Interview was conducted on February 20, 2007. In the Interview, it was agreed that claim 26 would be amended to include the limitation that the positioning element is configured to be grasped by a user, to further clarify the difference between the claimed embodiment and the Gildersleeve reference, which discloses hook and loop fasteners for maintaining a position of the device. Claim 9, which depends from claim 26, was also discussed

with respect to the term “integral.” Applicant’s representative pointed out that “integral” as used in the claim meant that at least a portion of the thermal energy source is disposed within the positioning element. It was agreed that an amendment to claim 9 was not required, because claim 9 would incorporate by reference the agreed amendments to claim 26, thereby rendering it allowable. (Note: Claim 9 is canceled in this response, rendering this issue moot. Furthermore, claim 26, as currently amended, includes the limitation that the thermal energy source is sealed within a cavity of the apparatus, thus clarifying the unitary nature of the claimed apparatus.) The Examiner also agreed that neither the sleeve 10 nor the dressing of Jenson suggested or disclosed the heat transfer element of claims 9, 10, 14, 16, and 26.

#### **Supplemental Teleconference regarding Patent No. 5,097,828**

An additional reference, Patent No. 5,097,828, issued to Deutsch (“Deutsch”) was provided by the Examiner on February 21, 2007. Applicant’s representative contacted the Examiner on February 22, 2007, to discuss the reference and it was agreed that in the interest of furthering prosecution the Deutsch reference will be addressed in this response, and amendments in addition to those previously discussed would include the limitations that the positioning element (handle) and other external components of the claimed embodiments would comprise a non-metallic substance. The Examiner agreed that such amendments would suffice to differentiate the claimed embodiments over all previously cited prior art, and Deutsch.

#### **Rejections under 35 U.S.C § 102**

Claims 2-5, 7 and 25 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,958,420, issued to Jenson. Claims 5 and 25 have been cancelled, rendering the rejection of these claims moot. Claims 2-4 and 7 are amended in this response to depend from

allowable claim 6, thereby rendering these claims allowable for at least the same reasons as claim 6. Accordingly, withdrawal of this rejection with respect to claims 2-4 and 7 is respectfully requested.

Claims 9-14, 16, 17 and 26 stand rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 6,352,550, issued to Gildersleeve et al. ("Gildersleeve"). Claims 9, 16, and 17 have been cancelled, rendering the rejection of these claims moot. Claim 26, from which claims 10-14 depend, is amended in this response to include the limitations that the positioning element comprises a non-metallic material configured to be grasped by a user, and the thermal energy source comprise a chemical compound sealed within a cavity substantially disposed within the positioning element and in fluid communication with an inner surface of the heat transfer element. No new matter was added by way of this amendment, which had been previously agreed upon during the Examiner Interview and Supplemental Teleconference, and for which support may be found at least in paragraphs 28-32, and 34 of the original specification as filed, as well as Figs. 1 and 2. To the extent this rejection applies to the amended claims, it is respectfully traversed.

Gildersleeve discloses flexible multi-joint thermal therapy pads having multiple lobes for placement over various joints of a body. The pads include inlet and exhaust ports for circulating a warm or cool fluid from a separate source through the pads. Hook and loop fasteners are used in some embodiments to stabilize such pads after they have been placed in a desired location.

The Examiner states that Gildersleeve discloses a positioning device (Fig. 4 # 17), that the thermal energy source and heat transfer element form an integral unit, and that the heat transfer element is also an insulating element. The Examiner cites Col. 5, line 64 – Col. 7, line 5,

Col. 9, lines 15-19, and Col. 10, line 54 – Col. 11, line 12, in support of these interpretations. Applicant fails to find support for these interpretations in the reference.

In particular, Gildersleeve neither discloses nor suggests a positioning element as described in the instant application. The element identified as #17 in Fig. 4 is not mentioned in the specification of Gildersleeve, and there is no support for the identification of such an element as a positioning device. While Gildersleeve does describe hook-and-loop fasteners for use in *maintaining* a position of the thermal energy pads, such fasteners do not correspond to a positioning element, such as a handle or grip, as disclosed in the instant application and would not serve the same function.

However, as agreed in the Examiner Interview, claim 26 is amended in this response to include the limitation that the positioning element is configured to be grasped by a user. Such a configuration advantageously facilitates the positioning of the apparatus in a desired location, as well as the application of desired pressure to the apparatus. No new matter has been added by way of this amendment, support for which may be found at least at paragraphs 28 and 34, and Figs. 1 and 2 of the application as filed.

Gildersleeve specifically describes a thermal therapy system as may be used with the disclosed multi-joint thermal therapy pads, as having a *separate* reservoir (e.g., an ice chest), which may be connected to the input and output of the thermal therapy pads (Fig. 3, further described at Col. 10, l. 54 – Col. 11, l. 12). Such a system explicitly contradicts the interpretation that the thermal energy source (fluid) and heat transfer element form an integral unit, as described in the instant application, and specified in the agreed amendments to claim 26.

Applicant further fails to discern any support for the statement that “the heat transfer element is also an insulating element” (p. 3 of the Office Action). A heat transfer element, as the

name implies, and as described in the instant application, conducts thermal energy. A thermal insulator, by definition, prevents or inhibits the conduction of thermal energy. Furthermore, there is no mention of insulation, or of an insulator, in Gildersleeve. For at least this reason, in addition to those previously discussed with respect to claim 26, claim 14 is patentable over Gildersleeve.

For the reasons described above, claims 10-14 and 26 are patentable over Gildersleeve. Accordingly, withdrawal of this rejection is respectfully requested.

### **Rejections under 35 U.S.C. § 103**

Claims 9, 10, 14, 16, and 26 stand rejected under 35 U.S.C. § 103 as being obvious over Jenson. Claims 9 and 16 are cancelled in this response, rendering their rejection moot. Claim 26, from which claims 10 and 14 depend, is amended in this response to include the limitations that the positioning element is configured to be grasped by a user, and that the thermal energy source comprise a chemical compound disposed within a cavity of the device. No new matter has been added by way of these amendments. To the extent the rejection may apply to the amended claims, it is respectfully traversed.

Jenson describes a wound dressing for treatment of burns. A dressing material saturated with tea tree oil is used to apply the tea tree oil to a wound to lower the intradermal temperature and prevent further tissue damage due to heat. The purpose of the dressing is to apply the burn wound treatment composition to a targeted area (Col. 4, ll. 15-20), and to also provide a protective moisture barrier to maintain moisture and create a sterile environment for healing (Col. 4, ll. 44-46). The burn wound composition may then be removed with water. The dressing is packaged within an envelope or other packaging material (Col. 8, ll. 27-30).

As discussed in the previously described Examiner Interview, the envelope of Jenson, identified by the Examiner as a surface of a heat transfer element, is actually a packaging material for the dressing. Jenson further fails to disclose or suggest any thermal energy source, as the saturated dressing will be maintained at room temperature, and simply theoretically absorb thermal energy from a burn wound. Jenson also fails to disclose or suggest any positioning element, as the Jenson device is simply a bandage saturated with a fluid or gel, and includes no other physical attributes, such as the positioning element, cavity, or heat transfer element required by claim 26, as amended.

For at least these reasons, and as agreed by the parties in the Examiner Interview, claim 26 is patentable over Jenson. Claims 10, and 14, which depend therefrom, are patentable for at least the same reasons. Accordingly, withdrawal of this rejection is respectfully requested.

#### **The Deutsch Reference**

Patent No. 5,097,828, issued to Deutsch ("Deutsch") was provided by the Examiner on February 21, 2007. Applicant's representative contacted the Examiner on February 22, 2007, to discuss the reference and it was agreed that in the interest of furthering prosecution the Deutsch reference will be addressed in this response. It was further agreed that the amendments described herein would suffice to patentably distinguish the claimed invention over Deutsch.

Deutsch discloses a battery-powered thermotherapeutic therapy device comprising a metal body configured to enclose at least one battery for powering a Peltier-effect apparatus disposed in a metal head. A fan is disposed in the head for venting exhaust gases. Depending on the direction of the current applied from the battery, the device may cool or heat a contact plate disposed in the head, and a gel-filled bag may also be attached to one end of the head to transmit

heat or cold from the contact plate to a subject's skin. In use, the device is activating by turning a knob to select either a heating or cooling function, and the head is applied to a portion of a subject's body. The head and body also function as a heat sink due to their metallic composition and large surface area. The device may also be configured to provide electrostimulation through the various metallic components thereof. A cap is provided at one end of the body for inserting and removing the batteries.

In contrast to Deutsch, the claimed embodiments of the instant invention, as described in amended claim 26 and claims 10-14 which depend therefrom, comprises a non-metallic positioning element (corresponding to a handle or body), and a thermal energy source comprising a chemical compound disposed within a sealed cavity of the device. Deutsch neither discloses nor suggests a non-metallic body, or chemical-based thermal energy source. Instead Deutsch specifically relies on an electrical current, and the heat-sink metallic components, to operate as described. For at least these reasons, claims 10-14 and 26 are patentable over Deutsch.

Furthermore, Deutsch neither discloses nor suggest a method according to claims 6 and 20 of the instant application. Claim 6 describes a method for inhibiting infection including disposing a surface of a heat transfer element in close proximity to a suspected area of infection, causing a rapid temperature change in the target area, discontinuing the temperature change, and assessing the area for occurrence of infection by evaluating a subject's level of discomfort and discontinuing treatment of the assessing reveals a rapid increase in discomfort followed by a gradual decrease in discomfort. In contrast to the method of claim 6, Deutsch neither suggests nor discloses use of the device for treatment of infection, or assessment of a subject's level of discomfort. For at least these reasons, allowed claim 6, as well as claims 2-4, and 7, which

depend therefrom, are patentable over Deutsch.


With respect to claim 20, Deutsch fails to suggest or disclose use of the device in a suspected area of *infection*, and further fails to suggest or disclose initiation of activation based on a temperature detector. Instead Deutsch requires manual activation of the device using a control knob. For at least these reasons, allowed claim 20, and claims 19, and 21-24 which depend therefrom, are patentable over Deutsch.

### Conclusion

Applicant believes this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account No. 50-0591 (Reference No. 17090/002001).

Respectfully submitted,

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